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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,697	11/16/2001	Robert Cosmo Di Luccio	14,853	2942
22827	7590	07/05/2005	EXAMINER	
DORITY & MANNING, P.A.			REICHLE, KARIN M	
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3761

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

①

<b>Office Action Summary</b>	<b>Application No.</b> 09/990,697	<b>Applicant(s)</b> DI LUCCIO ET AL.	
	<b>Examiner</b> Karin M. Reichle	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-22 and 44-77 is/are pending in the application.
- 4a) Of the above claim(s) 47-51 and 54-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-22, 44-46 and 52-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-9-05 has been entered.

### *Election/Restrictions*

2. Claims 47-51 and 54-77 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7-28-04 and 11-18-04.

Applicant's remarks with regard to claim 44 on page 1 of the 6-9-05 response are deemed moot since claim 44 is being treated on the merits. Claims 47-51 are still withdrawn because the melting points and viscosities of the medicinal composition made by the process of using a valve jet, i.e. the elected species, are not disclosed. While page 10, line 34-page 11, line 8 discloses the properties of the medicament compositions per se, other portions of the specification, e.g., page 5, lines 4 et seq and page 15, line 25-page 16, line 8 indicate the properties of the compositions are process dependent and Applicant has not pointed out where the application discloses the temperatures and shear viscosities of the compositions used in the

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process of making with a valve jet, i.e. the elected species, which temperatures and viscosities include those claimed in claims 47-51. It is further noted that Applicant elected without traverse. It is also noted that once claim 14 is indicated as allowable such claims will be entitled to consideration.

### ***Claim Language Interpretation***

3. With regard to claim 17, see page 4, lines 15-18 and page 5, lines 9-24 of the specification. "Medicaments" is interpreted in light of page 4, line 32- page 5, line 1, page 6, lines 24-28, and page 10, line 17-page 12, line 32. "Porous" is defined as set forth on page 6, line 34-page 7, line 2. "Effective amount" is defined as set forth on page 6, lines 13-17. "A pattern of a matrix of discrete segments" is interpreted in light of page 6, line 23-page 14, line 26 and page 16, line 24-page 17, line 6. Since "adjacent" has not been specifically defined, the broadest common, i.e. dictionary, definition will be used. The dictionary defines "adjacent" as "Close to, lying near", i.e. don't have to touch. The terminology "close to" and "lying near" is considered relative absent recitation of specific dimensions.

### ***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 14-16, 18, 20-22 and now 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayford '998.

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With regard to claims 14, 15, 21-22 and 44, see claim interpretation section *supra*, the Figures, col. 1, lines 4-6, col. 3, lines 69 et seq, col. 4, lines 10-26, i.e. the topsheet is 2, the absorbent material is 1, the backsheet is 5, an effective amount is disclosed at col. 2, lines 64 et seq, a medicinal composition is 3, 4 and 6 or just 3 and 4 and disclosed at col. 2, lines 39-60, the discrete segments are 4, a pattern is disclosed at col. 4, lines 30-36, i.e. “a portion of”, Figure 1 and 4, i.e. an array, and col. 2, lines 26-29, i.e. clusters, the volume of each discrete segment is disclosed at col. 2, lines 17-25 (the volume of a sphere is  $\frac{4}{3}\pi(r^3)$ ), i.e. 3 picoliters to 400 or to 200 nanoliters is equal to .000003-4 or -2 cubed mm and a capsule having a diameter of 200 microns has a volume of about .004 cubed mm. The medicinal composition is “adjacent” the porous material, see Claim Language Interpretation section *supra* and Response to Arguments section *infra*.

With regard to claim 16, see Figure 1, the spheres 4 stick out of matrix 6, i.e. extend above the surface of the matrix and the portions sticking out are “substantially” semi-spherical in cross section, see also col. 2, line 18.

With regard to claim 18, see again col. 4, lines 30-36, i.e. “a portion of” and col. 2, lines 26-29, i.e. clusters.

With regard to claim 20, the composition is claimed as including a filler. However, the specifics of the filler have not been disclosed. Therefore, the composition as disclosed at col. 2, lines 39-60 is considered to include such a “filler”.

***102/103 Rejections***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 17, 45-46 and 52-53 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hayford '998.

Claim 17 claims the frequency of positioning. See page 4, lines 15-18 and page 5, lines 9-24 of the specification. It is especially noted that as disclosed this is just the number of times an applicator "may" fire. Therefore this claim appears to be a product by process claim, i.e. the claiming of the frequency of possible firing of an applicator during the manufacture of the claimed product. This process does not appear to provide any further structure of the article than that already claimed. As set forth in MPEP 2113, it is the structure of the end product of the process which determines patentability not the process. Therefore, the Hayford device includes the same structure or obviously includes the same structure, as best understood.

Claims 45-46, as best understood, claim the viscosity of application to the topsheet. Therefore these claims also appear to be product by process claims, i.e. the claiming of the viscosity during the manufacture of the claimed product. This process does not appear to provide any further structure of the article or end product other than that already claimed, i.e. the viscosity of the discrete segments in the end product is not claimed. As set forth in MPEP 2113, it is the structure of the end product of the process which determines patentability not the process. Therefore, the Hayford device includes the same structure or obviously includes the same structure, as best understood.

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Claims 52-53, as best understood, claim a medicament which is applied to the topsheet in a pattern which comprises the discrete segments is melted and then is allowed to cool and solidify. Therefore these claims also appear to be product by process claims, i.e. the claiming of the state of a precursor material during the manufacture of the claimed product. This process does not appear to provide any further structure of the article or end product other than that already claimed, i.e. the specific temperature and solidity of the discrete segments in the end product are not claimed. As set forth in MPEP 2113, it is the structure of the end product of the process which determines patentability not the process. Therefore, the Hayford device includes the same structure or obviously includes the same structure, as best understood, see, e.g., col. 5, lines 8-33.

***Claim Rejections - 35 USC § 103***

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayford '998 in view of Vega '209 and Krzysik PCT '500.

Applicant claims the discrete segments located in a specific pattern not taught by Hayford. Applicant claims the discrete segments located in a specific pattern not taught by Hayford. Hayford only discloses application to a portion, e.g. clusters, an array, or the entire surface. However see Vega '209 at col. 29, lines 7-8 and col. 31, lines 19-32 and Krzysik at page 20, lines 19-29, i.e. interchangeability of a portion or the entire surface for the specific pattern as claimed. Therefore, to make the surface portion including segments 4 of Hayford the claimed specific pattern instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by Vega and Krzysik.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 14 –18, 20-22, 44-46 and 52-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 and 20-23 of copending Application No. 09/990,686(2003/0106605). Although the conflicting claims are not identical, they are not patentably distinct from each other because since the instant application has an effective filing date earlier than '686 but there was no administrative delay and Applicants could have avoided separate filings, the one way or *In re Vogel* test applies, i.e. are the claims of the instant application obvious in view of the claims of the '686 application. The answer is yes. With regard to claims 14-16, 18, 21-22 and 44, see claims 12-17 and 20-23 of the '686 application, as now amended and as best understood, and the definitions therein, e.g. what is considered a chemistry. Such claims teach substrates which are porous, chemistries, i.e. medicaments, chemistries which are discrete segments and provide skin separation, i.e. the substrate on which the chemistries are situated is a "topsheet", and an article which is absorbent and a diaper. While the absorbent material, backsheet, the position of the sheets and "an



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effective amount” are not explicitly claimed, it is well known in the absorbent article art that absorbent articles like diapers include a topsheet and a backsheet with an absorbent layer therebetween. Furthermore, it is well known to provide medicaments in amounts which provide the desired effect, i.e. the “effective amount”. Thus to employ the layers and position them as claimed as well as an effective amount of the medicament chemistry on the device of the ‘686 claims would be obvious to one of ordinary skill in the art in view of the recognition that the layers and positioning thereof are well known in diapers and the desire of the ‘686 claims to include a diaper and obvious in view of the recognition that a certain amount of the chemistry is require to be effective and the desire of the ‘686 claims to provide an effect with the chemistry. With regard to the limitations of the instant claims which are now broader than those claimed by the ‘686 claims, e.g. the volume, once an applicant has received a patent for a species on a more specific embodiment which would be the case if the ‘686 issued, he(she) is not entitled to a patent for the generic or broader invention. This is because the more specific anticipates the broader. See *In re Goodman*, supra. With regard to claims 17, 20, 45-46 and 52-53, see discussion supra in paragraphs 9 and 11, which rationales are repeated here.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 19 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 and 20-23 of copending Application No. 09/990, 686(2003/01066605) in view of Vega ‘209 and Krzysik ‘500. See discussion in paragraph 12 supra and claim 18 of ‘686. Also note col. 30, lines 40-41 of Vega. Therefore to make the selective application, i.e. a portion, of the ‘686 claims the

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specific claimed pattern instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by Vega and Krzysik.

This is a provisional obviousness-type double patenting rejection.

### ***Common Ownership***

12. Claims 14-22, 44-46 and 52-53 directed to an invention not patentably distinct from claims 12-17 and 20-23 of commonly assigned 09/990,686(2003/0106605). Specifically, see the double patenting rejections supra.

13. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/990,686(2003/0106605), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

14. The statement of common ownership filed 4-12-04 has been noted but is still insufficient to remove the issue of common ownership as it does not identify which invention is referred to by "at the time of the invention" and as set forth in MPEP 706.02(1)(2)(II) it must be shown that the ownership at the time the later invention was made. It is also noted that while Applicant has stated on page 15 of the 6-9-05 response that a terminal disclaimer and response to the common ownership issues are submitted with such response, at the time of this action no such submittal is evident as part of the 6-9-05 response.

#### ***Response to Arguments***

15. Applicants remarks with regard to the informalities in the 6-9-05 response have been noted. Applicant's remarks with regard to the provisional double patenting rejection have been noted supra. Applicant's remarks with regard to the prior art rejections have been considered but are deemed not persuasive in that such remarks are narrower than the claim language and the teachings of the prior art. Specifically, Applicant's interpretation of the term "adjacent" is narrower than its broadest common meaning, see Claim Language Interpretation section supra. It is again noted that such term was not explicitly defined anywhere in the application. Therefore, such language does not preclude contact as taught by Hayford because "adjacent" does not require the baby oil formulation directly touch the porous material. It is noted that the baby oil formulation does directly touch upon rupture of the capsules. The claims also do not otherwise require a lack of the capsule walls. Furthermore it is noted that the medicinal compositions as described on page 10, lines 27-34 and page 11, line 11-page 12, line 32 include components such as stabilizers, modifiers and agents of materials similar to those of the capsules

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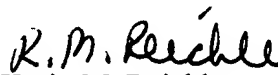
described by Hayford at, e.g., col. 3, lines 21-27. For example, the instant application discloses a medicament composition with a viscosity modifier including polyolefin resin materials or ethyl cellulose materials which materials can also be used as an encapsulating material, i.e. the application does not preclude such materials contacting the porous material.

*Conclusion*

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
June 23, 2005